Chapter 21

The Role of Pharmacovigilance Center in Sudan in Reporting Adverse Drug Reactions

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ABSTRACT

Pharmacovigilance is an active discipline, which is the study of structured mechanisms of the safety of medicines being used in clinical situations in large populations. In this chapter, the authors attempt to characterize the different types of Adverse Drug Reactions (ADRs) and related problems and mechanisms by which they cause harm to patients. They investigate the methods of detection of ADRs and various pharmacovigilance methods. The role and contributions of international organizations will be presented. The authors present the importance and need for education of healthcare professionals about pharmacovigilance and the proper reporting of ADRs for the purpose of efficient and safe use of medicines. The establishment of the Sudan pharmacovigilance center and how the system works will be discussed. Sources of data and actions taken since its inception are presented. The authors conclude by highlighting the problems and weaknesses of the system and ways to strengthen it.

INTRODUCTION

Drug safety is of paramount importance in the provision of health services. All around the world a vast amount of medicines are used as a result of doctors’ prescriptions, over the counter medicines, self medication, or illegal drug use. In all these settings, the safety of the user comes first. It was once said by Hippocrates in 460 BC “First do no harm,” and in 1785 the famous William Withering said “Poisons in small doses are good medicines, and good medicines in large doses are poisonous.”

Dr. Withering is the discoverer of Digitalis, a plant used for the treatment of heart failure, but has a narrow therapeutic window.

In the 20th century, great advances in drug therapy brought with them a growing awareness of the problem of drug safety, especially adverse drug reactions. In the 1960s, the thalidomide tragedy (responsible for the serious limb abnor-
mality in newborns, phocomelia) was the turning point in the development of modern drug regulation. Despite the introduction of these regulatory mechanisms, the number of licensed medicines that were withdrawn after marketing is increasing (Mann & Andrews, 2007). The question arises, why do we have to withdraw drugs, which were already passed by the regulatory bodies? To appreciate the scale of the problem, the number of medicines withdrawn from the market since the 1970s is more than 45. One of the major reasons is the fact that during drug development, a small number of participants is enrolled for preclinical and clinical tests. In the United Kingdom, for example, the number of participants is less than 2000 (Rawlins, et al., 1991). When the medicine is marketed, it will be used by large populations of ethnically different origins. The genetic differences among populations have been shown to be important in the appearance of adverse drug events. Other factors pertain to the nature of clinical trials, which are done on selected patients with one disease, whereas these medicines may be used in real situations in patients with co-morbidities and taking multiple drug therapies at the same time. Even nowadays, a large number of hospital admissions are due to adverse drug reactions, especially in the elderly (Pouyanne, 2002). The culmination of all the reporting of adverse drug events and the drug withdrawal after marketing and the regulatory acts around the world was the introduction of a new discipline, namely Pharmacovigilance.

Pharmacovigilance is the study, by structured mechanisms, of the safety of medicines already marketed under real conditions of clinical use in large populations of different ethnic origins. Health authorities and drug companies have actively established regulatory bodies to oversee the implementation of these regulations to minimize drug adverse events. Many drug agencies have established acts on drug safety. The FDA established the Prescription Drug User Fee Act (PDUFA) and in the United Kingdom the Committee on Safety of Medicines is responsible for investigating drug safety problems (Maan, 1987). Many studies have attempted to determine the incidence of ADRs in a variety of settings. Important studies were done, namely the Boston Collaborative Drug Surveillance Program (BCDSP), which made a great impact in the field of ADRs (1974). The Harvard Medical Practice study (1984), which reported high incidence of ADRs. Lazarou et al. (1998) and Wood et al. (1998) estimated that more than 160,000 fatal adverse reactions occurred in 1994 in the US. More recently, the number in the US has increased to 400,000 deaths in hospitalized patients alone.

**TYPES OF ADVERSE DRUG REACTIONS**

Adverse drug reactions are any injury resulting from medical intervention related to the use of a drug. It is usually an undesirable effect beyond the anticipated therapeutic effects occurring during clinical use (Primohamed, et al., 2004). At times ADRs can mimic the signs and symptoms of many diseases. For example, withdrawal symptoms of many drugs can be mistaken for symptoms of disease and infrequently missed by practicing doctors and pharmacists. It is, therefore, important for doctors and pharmacists to ask the question, can these symptoms be a result of medications taken by the patient before coming for consultation. The organs most affected by drugs are the skin, gastrointestinal tract, kidney, liver, and hemopoietic system. These are the main sites for iatrogenic disease, known as doctor-induced.

There are two types of adverse drug reactions, Type A and Type B.

Type A reactions are predictable, common, and usually dose-dependent. They result from exaggerated normal pharmacological or toxicological actions of the drug given in usual therapeutic doses. Examples are bradycardia with beta adrenergic
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